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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,728	CALDERON, MOISES	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4 and 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 as amended recites that the vent "further comprises two clamps removably attached to the cannulae to block a patient's blood flow until priming as desired." The recited cannulae have not been properly introduced into the claim (that is, stating that the second end of the cannula adapter bodies are adapted for attachment to a cannula does not positively recite the cannula) and thus lack proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. (Patent No. 4,662,355) in view of Leschinsky et al. (Patent No. 5,439,448).

Pieronne et al. disclose a system and method for pump-assisted myocardial revascularization without cardiopulmonary bypass comprising: surgically attaching a first cannula to the aorta (Fig. 1, element 14; Col. 2, lines 60-62); surgically attaching a second cannula the left atrium (Fig. 1, elements 1; Col. 2, lines 41-43); interconnecting the first and second cannulae with a first atrial-arterial shunt comprising a section of tubing having first and second ends and an interior (Fig. 1, element 3; Col. 2, lines 44-46); priming the shunt to remove air (Fig. 1, elements 4, 6, and 13; Col. 2, lines 47-48 & 66; Col. 3, lines 12-17); inserting the shunt tubing into a first peristaltic pump (Fig. 1, elements 7 & 8); and activating the pump to pump blood through the shunt and in parallel with the patient's heart pumping action (Col. 1, lines 6-11; Col. 7, lines 52-58). Regarding first and second cannula adapters, each with a vent for priming, see the Pieronne et al. Fig. 1 on the Office Action mailed 4/24/06 where examiner marked the structure considered to meet these claim requirements. Here, examiner considers that the Pieronne et al. "air purges" (i.e. vents for priming purposes) inherently include a sealing means for selectively opening and closing the vents. Without such sealing means, the vents would create deleterious open holes in the blood circuit.

Pieronne et al. do not explicitly disclose that the section of tubing is translucent. Leschinsky et al. disclose a method and apparatus for interconnecting blood-carrying tubing, cannulae, and/or external pumps and provide a teaching that blood-carrying tubing is most preferably formed of a clear material (Col. 6, lines 5-7). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Leschinsky et al. to modify the tubing of Pieronne et al. to be

translucent. The motivation would have been to enable the clinician to view the interior of the tubing to detect bubbles or other contaminants (Col. 6, lines 5-9).

In addition, Pieronne et al. do not explicitly disclose a cap removably attached to each vent. The system and method of Leschinsky et al. further includes vents for removing air from the a blood-carrying circuit, wherein the vents include removably attached caps for selectively opening and closing the vents during priming (Fig. 5, elements 28 & 32; Figs. 8, 9, & 10, elements 128 & 132; Col. 7, lines 39-55; Col. 9, lines 16-57). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Leschinsky et al. to modify the priming vents of Pieronne et al. to include removably attached caps. The motivation would have been to provide an easy, well-known means for closing the vents during normal pumping and for opening them during priming to allow air bubbles to escape to the external environment.

Regarding the limitation of Claim 13 that the "first peristaltic pump is one of a medical facility's existing peristaltic pumps from a cardiopulmonary bypass machine," the pump of Pieronne et al. is disclosed as the type conventionally used for extra-corporeal circulation and thus Examiner considers such the disclosed pump to be a medical facility's existing pump (Col. 2, lines 50-54).

In addition, with respect to the limitation of claim 13 that the method steps perform pump-assisted myocardial revascularization without cardiopulmonary bypass, Pieronne is directed to pump regulation circuits, including pumps utilized in a left or right side assistance system (see, for example, col. 1, lines 9-43). Examiner considers such

a left or right assistance system to be performing myocardial revascularization (see col. 1, lines 19-22) without cardiopulmonary bypass (the system is used assist the heart rather than bypass the heart, and patients utilizing the assistance system can be weaned off the device as the myocardium recovers; see col. 1, lines 26-43).

Regarding Claim 14, it seems inherent from Pieronne et al.'s description of the vents (Fig. 1, elements 4 & 13) as "air purges" that the vents are opened at appropriate times to allow the passing flow of blood to force out (i.e. purge) any trapped air.

5. Claims 3, 15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and further in view of Aboul-Hosn et al. (Patent No. 6,935.344).

As related above with respect to claims 1 and 13, Pieronne et al. disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Pieronne et al. do not explicitly disclose that the pump is placed within one meter of the patient or that the tubing is no longer than two meters. Aboul-Hosn et al. disclose systems and methods for left and right side heart assistance including the use of shunt tubing and peristaltic pumps (Fig. 5; Col. 18, lines 41-54). Additionally, Aboul-Hosn et al. teach that it is important to bring the pump as close to the patient as possible and to minimize priming volume, the volume of the support system that is external to the patient (Col. 5, lines 2-16; Col. 17, lines 15-26). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Aboul-Hosn et al. to modify the heart support system of Pieronne et al. to

include placement of the pump within one meter of the patient and to utilize tubing that is no longer than two meters. The motivation would have been to provide well-known advantages of minimizing the distance and time that blood travels outside the body, such as preventing the occurrence of hemolysis and eliminating the necessity of cooling or warming the blood (Col. 17, lines 24-39).

In addition, with respect to the limitation of claim 20 that the method steps perform pump-assisted myocardial revascularization without cardiopulmonary bypass, Pieronne is directed to pump regulation circuits, including pumps utilized in a left or right side assistance system (see, for example, col. 1, lines 9-43). Examiner considers such a left or right assistance system to be performing myocardial revascularization (see col. 1, lines 19-22) without cardiopulmonary bypass (the system is used assist the heart rather than bypass the heart, and patients utilizing the assistance system can be weaned off the device as the myocardium recovers; see col. 1, lines 26-43).

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. as applied to claim 13 above, and further in view of Runge (Patent No. 5,743,845).

As related above, Pieronne et al. disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Pieronne et al. further disclose simultaneous right side assistance that utilizes right side cannulation sites and a second atrial-arterial shunt and peristaltic pump (Fig. 1, elements 4a, 7a, 8a, 13a, & 16-18; Col. 2, lines 66-68; Col. 3, lines 1-11). Pieronne et al. disclose that the

third cannula is surgically attached to the pulmonary artery, but do not explicitly disclose that the fourth cannula is attached to the right atrium. Instead the fourth cannula is described as attached to "the outlet of the organ, such as the vena cava." Runge discloses a system and method for left and right side heart support that omits the need for an oxygenator of a conventional cardiopulmonary bypass system (Figs. 4 & 5; Col. 3, lines 24-27). Runge further provides a teaching that the cannulation sites most preferred by surgeons "will be from the right atrium to the pulmonary artery, and from the left atrium to the aorta" (Col. 3, lines 9-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Runge to modify the heart support system of Pieronne et al. to include attaching the fourth cannula to the right atrium. The motivation would have been to provide the cannulation configuration most preferred by surgeons.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and Runge as applied to Claim 16 above, and further in view of Aboul-Hosn et al.

Comments made above in rejection of Claims 3, 15, and 20 regarding tubing length and placement of the pump within one meter of the patient apply here as well.

8. Claims 4, 6, 8, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and further in view of Rawles et al. (Patent No. 6,890,316).

As related above, Pieronne et al. disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Comments made above in rejection of Claims 1, 2 and 13 apply here as well. However, Pieronne et al. do not explicitly disclose that the above-described atrial-arterial shunts are packaged in a sealed, openable container having a sterile interior. Rawles et al. disclose a tubing set for a blood handling system that includes placing the tubing in a sealed, openable container having a sterile interior (Fig. 5, elements 60 & 65). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Rawles et al. to modify the heart support system of Pieronne et al. to include such sterilized packaging of the shunt prior to its use in the pumping system. The motivation would have been to prevent contamination of the tubing, and possible subsequent contamination of the patient's blood, while handling it before connection to the cannulae.

With respect to the limitation of claim 4 that the vent "further comprises two clamps removably attached to the cannulae to block a patient's blood flow until priming as desired," Pieronne et al. fails to explicitly disclose that the left side assistance system may include such clamps. However, it is well known in the art to utilize clamps for controlling fluid flow in extracorporeal tubing systems (for example, see Leschinsky et al. in the background section describing that extracorporeal tubes are each clamped to control fluid flow in a prior art priming procedure; col. 1, lines 40-45. Examiner notes that class 604/250 contains 400 patents or publications relating to such clamps for pinching conduits or tubes to control flow of material to or from the body). More

particularly, Rawles et al. teaches that all of the valves of the extracorporeal tubing set used in the priming circuit preferably comprise well-known pinch clamps that engage an exterior surface of the tubing (see col. 6, lines 23-39; see also col. 9, lines 65-66). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the sterilized packaging of Pieronne to include pinch clamps as taught by Rawles in order to supply medical personnel with all equipment necessary or desired for the priming procedure.

9. Claims 7, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al., and further in view of Rawles et al. as applied to Claims 4-6, 8, 9, and 11 above, and further in view of Aboul-Hosn et al.

Comments made above in rejection of Claims 3, 15, and 20 regarding tubing length that is no longer than two meters apply here as well.

Response to Arguments

10. Initially, Examiner notes that the Second Non-Final Office Action mailed 4/24/06 was proper. As explained by Examiner Alexander, the previous indication of allowability was withdrawn in view of the newly discovered reference(s) to Pieronne. In view of the newly discovered reference, it was proper to withdraw the previous indication of allowability and apply the reference to the claims. In addition, Examiner Alexander explicitly did not make the Second Action final since the new grounds of rejection were

not necessitated by Applicant's amendment. Rather, Examiner Alexander appropriately issued a second non-final office action.

11. Applicant's arguments filed 7/25/06 have been fully considered but they are not persuasive.

12. In particular, Applicant argues that there is no teaching in any of the cited patents to combine them in the manners proposed in the Office Action mailed 4/24/06, and that the examiner's conclusion of obviousness is based upon improper hindsight reasoning.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references are found in the references themselves and are in the knowledge generally available to one of ordinary skill in the art as described in the rejections above. For example, with respect to claims 1, 13, and 20, the motivation to modify the tubing of Pieronne et al. to be translucent is found within the teaching reference, Leschinsky et al. (the motivation would have been to enable the clinician to

view the interior of the tubing to detect bubbles or other contaminants (Col. 6, lines 5-9)).

In response to the argument of improper hindsight, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

13. Applicant also argues that Pieronne's "air purges" are unclear terms, and that they are not necessarily priming vents (see page 11 of Response filed 7/25/06). Examiner respectfully disagrees. Initially, Examiner notes that every patent is presumed valid (see 35 U.S.C 282), and thus the terms of Pieronne are presumed to be clear and definite as require by 35 U.S.C. 112. Further, the broadest reasonable interpretation of the claim term "vent" encompasses any structure including an opening serving as an outlet for air, smoke, fumes, etc... (see attached definition of "vent" from dictionary.com). As shown in Figure 1 of Pieronne, the air purges 4 and 13 provide such an opening. Further, it is apparent from the specification of Pieronne that the air purging means provide a structure to rid or remove air from the assistance circuit of Pieronne (see attached definition of "purge" from dictionary.com). It is apparent from these ordinary and accustomed terms of "purge" and "vent" that Pieronne's air purges

necessarily serve as openings to rid or remove air from the assistance circuit of Pieronne.

14. Applicant also argues that Pieronne does not teach or suggest that the air purging can be done by patient's own blood, as required by amended claim 1 (see page 11 of Response filed 7/25/06). However, the claim recitation "for priming the vent with blood flow from the patient" as recited in claim 1 is merely a statement of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the intended use recitation does not result in a structural difference between the claimed invention and Pieronne, such a recitation is not given patentable weight.

15. Applicant also argues that neither Pieronne nor Leschinsky perform myocardial revascularization without cardiopulmonary bypass, as now recited in the body of method claims 13 and 20 (see page 12 of Response filed 7/25/06). Pieronne is directed to pump regulation circuits. Although Pieronne's teachings apply to the regulation of a by-pass circuit as pointed out by Applicant's citation of col. 1, lines 6-7, Pieronne is also directed to pumps utilized in a left or right side assistance system (see, for example, col. 1, lines 9-43). Examiner considers such a left or right assistance system to be performing myocardial revascularization (see col. 1, lines 19-22) without

cardiopulmonary bypass (the system is used assist the heart rather than bypass the heart, and patients utilizing the assistance system can be weaned off the device as the myocardium recovers; see col. 1, lines 26-43).

16. With respect to claims 3 and 15, Applicant argues that Examiner "fluffs off" the subject matter contained therein without any clear teachings from the cited references (see page 12 of Response filed 7/25/06). However, such subject matter was given proper consideration; Examiner cited and applied the teachings from Aboul-Hosn. Aboul-Hosn provided a teaching and motivation for placing the pump within one meter of the patient or the tubing no longer than two meters (that is, Aboul-Hosn et al. teach that it is important to bring the pump as close to the patient as possible and to minimize priming volume, the volume of the support system that is external to the patient (Col. 5, lines 2-16; Col. 17, lines 15-26)).

17. Lastly, Applicant argues that claim 16 was rejected without finding Applicant's claimed fourth cannula attached to the right atrium - rather, that Examiner "flew by that feature" (see page 12 of Response filed 7/25/06). Again, such subject matter was given proper consideration; Examiner cited and applied the teachings from Runge. Pieronne et al. disclosed a right-assistance system in addition to the left assistance system, the right assistance system including third and fourth cannulae. The third cannula of Pieronne is surgically attached to the pulmonary artery, but the fourth cannula is described as attached to "the outlet of the organ, such as the vena cava." Thus,

Pieronne fails to disclose that the fourth cannula may be instead attached to the right atrium. However, Runge provided a teaching and motivation for attaching the fourth cannula of Pieronne to the right atrium. Runge discloses a system and method for left and right side heart support (Figs. 4 & 5; Col. 3, lines 24-27), and teaches that the cannulation sites for right side heart support most preferred by surgeons "will be from the right atrium to the pulmonary artery, and from the left atrium to the aorta" (Col. 3, lines 9-11). Thus, Examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Runge to modify the heart support system of Pieronne et al. to include attaching the fourth cannula to the right atrium. The motivation would have been to provide the cannulation configuration most preferred by surgeons, as taught by Runge (Col. 3, lines 9-11).

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRK
9/20/06

George Manuel
Primary Examiner